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PATENT

Attorney Docket No. 18781-007320

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Helen H. Hobbs, *et al.*

Application No.: 09/989,981

Filed: November 20, 2001

For: ABCG5 AND ABCG8: COMPOSITIONS AND METHODS OF USE

Examiner: Christopher J. Nichols

Art Unit: 1647

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the First Restriction Requirement, which is set forth on page 2 of the Communication dated November 20, 2002, Applicants elect, with traverse, to prosecute the claims of Group I, claims 1-21 and 36-37, drawn to isolated nucleic acid molecules encoding an ABCG8 polypeptide, method for making an ABCG8 polypeptide comprising an isolated nucleic acid molecule, expression cassettes and cells comprising the same. In response to the Second Restriction Requirement, which is set forth on page 5 of the Communication dated November 20, 2002, Applicants elect, with traverse, to prosecute the sequence of Group F, drawn to the sequence of SEQ ID NO: 6. Applicants' election is made with traverse as examination of the subject matter recited in the claims of Groups I-VII and the sequences of Groups A-H would not place a substantially greater burden on the Examiner.

Applicants respectfully traverse the Restriction Requirement on at least two grounds. First, the Second Restriction Requirement does not follow the procedure set forth in 37 CFR § 1.141-1.146 and the corresponding sections of the MPEP for handling generic claims. According to 37 CFR § 1.141, an applicant may not claim two or more independent and distinct inventions in a single application "except that more than one species of an invention . . . may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim" (emphasis added). Thus, "[w]here an application contains a generic claim for all of the disclosed species, a restriction usually is not proper." *R2 Medical Systems, Inc. v. Katecho, Inc.*, 931 F. Supp. 1397, 1436, n. 16, n. 17 (N.D. Ill. 1996).

The procedure for handling applications that include generic claims is set forth in 37 CFR § 1.146. This rule provides that "[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable." As stated in MPEP § 809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141." Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable.

In the instant case, the required procedure is not being followed. Claim 1 is a ***proper*** generic claim within the requirements set forth in 37 CFR § 1.141. More particularly, claim 1 satisfies the definition of a generic claim as set forth in MPEP § 806.04(d), in that this generic claim does not include limitations that are not present in all claims that depend from it.